

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Claims 54 and 56-71 were rejected under 35 U.S.C. §103(a) as being unpatentable over Wakikaido et al. (6,451,014) in view of Jackson et al. (5,383,874). The Applicant traverses this rejection. Claims 54 and 71 call for “a light located on the medical device and electrically coupled to the power source.” Claim 54 calls for “a switch located on the medical device for activating the delivery of electrical power from the power source, wherein the light is visible when power is being delivered.” Claim 71 calls for “an activator located at the handle for activating the delivery of power from the power source, wherein the light is visible when power is being delivered.” These elements are missing from the prior art references.

Jackson et al. teach a system for performing ablation that may include a flashing light and audible alarm to act as a warning signal that a phase shift has occurred. Wakikaido et al. teach an electrode device which does not include a switch or a light. Jackson et al. do not teach or suggest that the flashing light is located on the device. While the location of the light and alarm are not specified, the reference as a whole suggests that this warning signal would be located on the generator. All of the components and displays relating to power are located on the generator, there are no displays on the device, and there is no teaching or suggestion that information relating to the power could be sent from the generator to the device. Finally, the warning signal includes an audible alarm in addition to a flashing light, suggesting that the light is not readily visible on the device but rather is accompanied by an audible alarm in order to alert that user to the warning when the user is not facing the generator. A light on a generator requires an operator to be facing the generator to observe whether the light is on or off. A light provided on the medical device as called for by claims 54 and 71 is more readily visible by the operator because it is in the operative field. Because neither Wakikaido et al. nor Jackson et al. teach or suggest a light located on the medical device, this element is missing from claims 54 and 71 and the rejection of these claims should be withdrawn.

The Applicant also disagrees with the position that changing the location of the switch would not be patentable because it would not have modified the operation of the device. A switch which is located on the device as claimed can be easily and instantaneously activated by the operator. In some cases, the operator may even be able to activate the switch using a single hand while holding the device. In contrast, a switch which is located on a generator requires, at the very least, that the operator activate the switch using a second hand. This may be

cumbersome because during a procedure such as ablation, the operator's second hand may be occupied, such as retracting tissue at the procedure sight. Furthermore, the operator may need to turn away from the field of the procedure to operate a switch which is separate from the device. The activation of a switch away from the device may also be complicated by the need to maintain a sterile environment during the ablation procedure, where the switch on the generator is likely outside of the sterile operating field. Because of these difficulties, it may even be necessary for a second person to activate the switch at the request of the operator, making the activation of the switch more difficult for the operator and less instantaneous than a switch located on the device. Therefore a switch located on the device offers significant functional advantages over a switch on a generator and is more than a simple design choice but rather modifies the operation of the device.

Furthermore, the switch, the light and the power source of Jackson et al. are not related to each other as called for in claims 54 and 71. The claims call for a light coupled to a power source and a switch or activator "for activating the delivery of electrical power from the power source, wherein the light is visible when power is being delivered." The switch or activator of Jackson et al. referred to in the Office Action appears to be the "RF Power Control ON" switch on the generator. While not described in the reference, this switch appears to be a power switch for the generator. There is no teaching or suggestion that the switch is for activating delivery of power, wherein the light is visible when power is being delivered. Furthermore, because the flashing light of the warning signal is triggered by a phase shift, such a warning signal may or may not be activated during any particular use of the device and therefore whether the light is visible is unrelated to the activation of any switch in Jackson et al. but rather is separately activated by the system. This element of the claims is therefore also missing from Jackson et al.

In conclusion, neither Wakikaido et al. nor Jackson et al., alone or in combination, teach "a light located on the medical device and electrically coupled to the power source" as called for in claims 54 and 71. Neither reference teaches a switch or activator located on the device or handle as called for in these claims. Finally, neither reference teaches a switch or activator "for activating the delivery of power from the power source, wherein the light is visible when power is being delivered."